

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 19-24 and 28-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al. (5,646,046). This rejection was applied in the previous Office Action (mailed 10/01/09). It remains in effect. Please see Response to Arguments below.

3. Claims 19-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Burns et al. (US 2003/0054542). This rejection was applied in the previous Office Action (mailed 10/01/09). It remains in effect. Please see Response to Arguments below.

### ***Response to Arguments***

4. Applicant's arguments filed 01/04/10 have been fully considered but they are not persuasive. Applicant has argued that the instrument of Fischer is not a quality control device (Page 8 of Arguments):

“Fischer concerns a method and instrument for automatically performing analysis relating to thrombosis and hemostasis by spectrophotometry. The instrument of Fischer is **not a quality control device for control bloods**. Instead, the instrument of Fischer conducts different assays to measure hemostasis or thrombosis parameters of samples in test wells using particular reagents. Any disclosure of means for refrigeration, means for heating, means for stirring, and means for sampling disclosed in Fischer **is limited to samples and/or reagents, not control bloods**. The only disclosure related to quality control in Fischer is related to monitoring the performance of the method and evaluating the validity of the reported data for the sample. Such disclosure is not relevant to the instantly claimed device. Finally, being directed to a different kind of testing, the instrument of Fischer naturally does not comprise means for sampling bloods or re-suspending of the cells.”

The Examiner notes that the highlighted passages are intended use arguments. The Examiner reminds Applicant that the claims are drawn to a device, not a method. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant has also argued that Fischer does not comprise means for sampling bloods or resuspending of the cells. The Examiner respectfully disagrees and notes that Applicant's sampling means as disclosed in the Specification is simply a needle. This is the same device taught by Fischer. See column 9 of Fischer and Paragraph 3 of the Previous Office Action.

5. Applicant has also argued that the device of Burns is not a quality control device (Pages 8-9 of Arguments):

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“Again though, the device in Burns does not teach the presently claimed quality control device **for control bloods incorporated into a blood analyzer**. The Burns device is designed for providing specimens to reaction receptacles within an automated analyzer to conduct nucleic acid-based assays. The device **works on serum and not on whole blood**. The means disclosed therein are **for samples and/or reagents and not control bloods**. Accordingly, the Burns device teaches nothing about control bloods. Moreover, no means for re-suspension of the cells is disclosed by Burns. Further, there is no means for storing control bloods inside the analyzer.”

The Examiner again notes that the highlighted passages are intended use arguments. The Examiner reminds Applicant that the claims are drawn to a device, not a method. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant has also argued that Burns does not comprise means for storing bloods or means for resuspending the cells. The Examiner respectfully disagrees and notes that Applicant's resuspension means as disclosed in the Specification is a vortex stirrer, rocker or inverter (Paragraph 0065). Burns teaches an orbital shaker in Paragraph 0326. The Examiner submits this is a vortex stirrer. Applicant has argued that Burns does not teach means for storing blood by refrigeration. The Examiner respectfully disagrees and submits Burns recites multiple means for storage including the cooling bay (900) and a Peltier device (Paragraphs 0241-0258).

***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DWAYNE K. HANDY whose telephone number is (571)272-1259. The examiner can normally be reached on M-F 11:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dwayne K Handy/  
Examiner, Art Unit 1797

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797

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